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### VIA COURIER

May 3, 2004

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
HFA-305, Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

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### SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR §10.20 and §10.30, as provided for in 21 CFR §314.93 and Section 505(j)(2)(c) of the Federal Food, Drug, and Cosmetic Act, to request the Commissioner of the Food and Drug Administration to declare that the drug product, **Glyburide and Metformin HCl Tablets for Oral Suspension**, 1.25 mg/250 mg; 2.5 mg/500 mg; 5 mg/500 mg, is suitable for submission as an abbreviated new drug application (ANDA).

#### A. Action Requested

The petition is submitted for a change in dosage form of the drug product from "Tablets" to "Tablets for Oral Suspension." The reference listed drug product upon which this petition is based is Glucovance® (glyburide and metformin HCl) Tablets 1.25 mg/250 mg; 2.5 mg/500 mg; 5 mg/500 mg manufactured by Bristol-Myers Squibb Company. Glyburide and Metformin HCl Tablets for Oral Suspension will be marketed as tablets for oral suspension in dosage strengths of 1.25 mg/250 mg, 2.5 mg/500 mg, and 5 mg/500 mg. The drug, the route of administration, and the recommendations for use are the same as those of the listed drug product. The proposed product would differ only in dosage form from Bristol-Myers Squibb Company's marketed product.

The proposed drug product is expected to demonstrate bioequivalence to the listed product; data will be submitted at a later date.

2004P-0209

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**B. Statement of Grounds**

Glyburide and Metformin HCl Tablets for Oral Suspension are presented for administration by solubilizing/dissolving a single tablet in a specified amount of water.

The new dosage form is expected to be a viable alternative for patients who have problems swallowing the tablet dosage form.

The proposed product will differ from the listed drug only in dosage form. The indications, strengths, route of administration, intended patient population, and recommendations for use will remain the same as the Bristol-Myers Squibb Company-marketed product. Therefore, there will be no difference in the safety and efficacy of the proposed Tablets for Oral Suspension.

The package insert for Bristol-Myers Squibb Company's Glucovance<sup>®</sup> Tablets is provided in Attachment 1 of this petition. The draft package insert for the proposed Glyburide and Metformin HCl Tablets for Oral Suspension is provided in Attachment 2.

**C. Pediatric Use Information**

In December of 2003, Congress passed the Pediatric Research Equity Act (PREA) that amended the Federal Food, Drug and Cosmetic Act (The Act) to provide the Agency authority to require drug firms to study certain drugs in pediatric patients, if the Agency felt that such study would provide beneficial health data for that patient population. Requirements are outlined in the PREA and with concepts provided in the Draft Guidance for Industry [Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)), dated November 2000].

Section 505B(a)(4)(A)(iii) of The Act (as amended by PREA) provides a provision for a waiver from providing assessments of pediatric use of a drug if:

(iii) the drug or biological product --

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

The petitioner hereby requests that a waiver from the conduct of pediatric studies of Glyburide and Metformin HCl Tablets for Oral Suspension for all age groups be granted for this petition.



The reference listed drug product is currently available in a conventional immediate-release tablet and is not, according to the approved labeling, recommended for use in pediatric patients. For this reason, the change in dosage form to a tablet for oral solution from an immediate-release tablet would not likely result in use in the pediatric population. In addition, the combination of Glyburide/Metformin does not appear on the FDA listing of drug products for which studies may provide health benefits to the pediatric population. The proposed product, designed to provide a more convenient dosage form for adult patients that cannot swallow tablets, would therefore, not represent a meaningful benefit over existing therapies for the pediatric patient. In addition, based on the labeling of the proposed product it is not likely to be used in a substantial number of pediatric patients.

For the reasons stated above and consistent with the provisions of the Pediatric Research Equity Act of 2003, the petitioner respectfully requests that this waiver be granted.

**D. Environmental Impact**

An environmental assessment report on the action requested in this petition is not required under 21 CFR §25.31.


**E. Economic Impact**

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

**F. Certification**

The undersigned certifies that to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,



Nicholas M. Fleischer, R.Ph., Ph.D.  
Vice President  
Clinical Pharmacology & Biopharmaceutics  
THE WEINBERG GROUP INC.

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Enclosure

cc Gary Buehler, Director, Office of Generic Drugs  
Emily Thakur, Office of Generic Drugs

